

### **REMARKS**

Claims 1-20, 22 and 24-27 are currently pending. Claims 2-4 and 20 are currently amended. Claims 21 and 23 were previously canceled. As a result of a previous restriction requirement, claims 25-27 have been withdrawn, leaving claims 1-20, 22 and 24 under consideration in this application.

#### **Rejection of Claims 2-17 Under § 112**

The Examiner indicates that claims 2-17 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. However, the Examiner discusses claims 2-7 and 20 instead. It is unclear whether the Examiner is also rejecting claims 8-17 under § 112, and if so, what the rationale is for the rejection. Applicants respectfully request the Examiner to positively include or exclude these claims from his § 112 rejection and provide the reasoning for any included claims in order to clarify the record in this case.

Regarding claims 2-4, the Examiner has indicated that it is not clear as to what frame of reference is being used to establish the location of the sub-elements of the claims. Claims 2-4 have been amended to make clear that the frame of reference terms used in claims 2-4 apply when the prosthesis body is fixed to the vertebral body. The anatomy of various vertebrae and associated frame of reference descriptions are provided in the specification as filed, for instance on page 9, line 20 through page 11, line 10.

Regarding claims 5-7, the Examiner has indicated that the term “adapted and configured” in the claims is a relative term that renders the claim indefinite. The Examiner recites the following support for his position: (1) “The term ‘adapted and configured’ is not defined by the claim;” (2) the specification does not provide a standard for “ascertaining the requisite degree;” and (3) one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. (Office Action at p. 4).

First, there is no requirement in § 112 or the case law interpreting it that a claim contain a definition for any of its terms. The term “adapted and configured” can easily be understood by a skilled artisan.

The Examiner's second point makes no sense: Of what (or for what) must the specification provide the standard for ascertaining a requisite degree?

Finally, there can be no serious argument that a skilled artisan would not understand the scope of each of claims 5-7 simply because of the use of the structural limitation "adapted and configured" to replace a specified part of the anatomy. When read in light of the specification, the scope of each of these claims is clear. There is no need for these claims to specifically recite any more structure than each of them already does in order to meet the requirements of § 112. The Examiner's rejection of claims 5-7 under § 112, second paragraph, is inappropriate and should be withdrawn.

Regarding claim 20, the Examiner has indicated that the claim should be reworded in for the form of a Markush group. Accordingly, claim 20 has been so amended.

**Rejection of Claims 1-8, 10, 18-20, 22 and 24 Under § 102(b) Over Any of Zang, Wall, Homsy or Morgan**

The Examiner rejected claims 1-8, 10, 18-20, 22 and 24 under 35 U.S.C. § 102(b) over any of Zang US 5,314,486 ("Zang"), Wall US 4,693,722 ("Wall"), Homsy US 4,778,472 ("Homsy") or Morgan US 4,917,701 ("Morgan"). The Examiner contends that the prostheses disclosed by each of these references (1) "is structurally similar to that illustrated by applicant" and (2) "is capable of performing the function of replacing all or a portion of the natural facet joint." (Office Action at pp. 5-6) The Examiner's first point, however, misstates the requirements for anticipation. The question of anticipation under § 102 is not whether the reference discloses a device that is "structurally similar" to the device illustrated in Applicant's figures but is rather whether the reference discloses each and every feature recited by the claims.

The Examiner's second point is even more remarkable. Wall, Homsy and Morgan disclose temporomandibular joint prostheses. Zang discloses a metatarso-phalangeal joint prosthesis. The Examiner was not able to point to any disclosure in any of these references to support his contention that each of these prostheses could be implanted into a patient's spine to perform the function of replacing all or a portion of a natural facet joint.

Claim 1 recites a prosthesis with a prosthesis body accommodating fixation to a vertebral body at or near a pedicle and without support by a lamina and an artificial facet joint structure

carried by the prosthesis body at a location spaced from the fastening element, the artificial facet joint structure being adapted and configured to replace all or a portion of a natural facet joint. The Examiner's action does not explain how any of these references discloses these elements. In fact, none of these references discloses every element of claim 1. Claim 1, and claims 2-8, 10, 18-20, 22 and 24 depending directly or indirectly from it, are therefore patentable over each of these references under § 102(b).

With respect to at least claims 10-14, 18, 22 and 24, the Examiner's remarks appear to be limited to Zang and not at all to Wall, Homsy or Morgan. Applicant respectfully requests the Examiner to clarify the basis of his rejection of these claims in the next action so that the record will be unambiguous in any appeal.

#### **Rejection of Claims 8 and 10-17 Under § 103(a) Over Zang and Carignan**

The Examiner rejected claims 8 and 10-17 under 35 U.S.C. § 103(a) as being unpatentable over Zang as applied to claim 1 and further in view of Carignan US 4,955,916 ("Carignan"). As discussed above, the Examiner never did apply Zang or any other reference specifically to claim 1. Nonetheless, Carignan fails to cure the deficiencies of Zang with respect to the elements of claim 1, from which each of these claims depends. Claim 1 recites a prosthesis with a prosthesis body accommodating fixation to a vertebral body at or near a pedicle and without support by a lamina and an artificial facet joint structure carried by the prosthesis body at a location spaced from the fastening element, the artificial facet joint structure being adapted and configured to replace all or a portion of a natural facet joint. Neither Zang nor Carignan, alone or in combination, discloses any of these elements. For at least these reasons, the Examiner's rejection of claims 8 and 10-17 under § 103(a) over Zang and Carignan is improper and should be withdrawn.

#### **Rejection of Claim 9 Under § 103(a) Over Zang and Hamilton**

The Examiner rejected claim 9 under 35 U.S.C. § 103(a) as being unpatentable over Zang as applied to claim 1 and further in view of Hamilton US 5,314,492 ("Hamilton"). As discussed above, the Examiner never did apply Zang or any other reference specifically to claim 1. Nonetheless, Hamilton fails to cure the deficiencies of Zang with respect to the elements of claim

**Amendments to Claim 11**

Claim 11 is currently amended to clarify the invention being claimed therein.

**CONCLUSION**

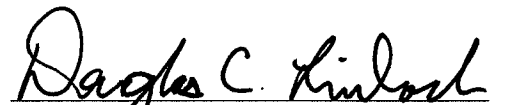
In light of the remarks set forth above, Applicants believe that all claims are now in condition for allowance. Applicants respectfully solicit the Examiner to expedite the prosecution of this patent application to issuance. Should the Examiner have any question, the Examiner is encouraged to telephone the undersigned at (650) 212-1700.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 50-4050 referencing docket no. 10002-701.407. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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